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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,377	10/20/2004	Victor V. Lobanenkov	230295	2372

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EXAMINER	
GUSSOW, ANNE	
ART UNIT	**PAPER NUMBER**
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,377	LOBANENKOV ET AL.	
	Examiner	Art Unit	
	Anne M. Gussow	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group 1 is drawn to a nucleic acid and a method of using the nucleic acid. All of the other Groups are drawn to additional products and methods that do not comprise combinations of Groups 1. Therefore restriction is proper.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 9, 13, 23 in part, and 24 drawn to an isolated or purified nucleic acid, vector and host cell encoding human BORIS and a method of diagnosing cancer or a predisposition to cancer in a male mammal by detecting a nucleic acid encoding BORIS. Claim 23 will be examined only to the extent that it relates to a nucleic acid.

Group II, claim(s) 3, 4, 10, and 14, drawn to an isolated or purified nucleic acid complementary to human BORIS.

Group III, claim(s) 5, 6, 11, and 15, drawn to an isolated or purified nucleic acid encoding a non-human BORIS.

Group IV, claim(s) 7, 8, 12, and 16, drawn to an isolated or purified nucleic acid complementary to a non-human BORIS.

Group V, claim(s) 17 and 18, drawn to an isolated or purified polypeptide molecule encoding human BORIS.

Group VI, claim(s) 19 and 20, drawn to an isolated or purified polypeptide molecule encoding a non-human BORIS.

Group VII, claim(s) 21 and 22, drawn to a monoclonal antibody specific for a region of human BORIS and the cell line that produces the antibody.

Group VIII, claim(s) 23 in part, and 25, drawn to a method of diagnosing cancer in a male mammal by detecting a polypeptide encoding BORIS. If Group VIII is elected, these claims will be examined only to the extent that they relate to a polypeptide.

Group IX, claim(s) 26 in part, and 27, drawn to a method of predicting a predisposition to cancer in an offspring of a male mammal by detecting a nucleic acid encoding BORIS. If Group IX is elected, these claims will be examined only to the extent that they relate to a nucleic acid.

Group X, claim(s) 26 in part, and 28, drawn to a method of predicting a predisposition to cancer in an offspring of a male mammal by detecting a polypeptide encoding BORIS.

If Group X is elected, these claims will be examined only to the extent that they relate to a polypeptide.

Group XI, claim(s) 29 in part and 30, drawn to a method of diagnosing cancer or a predisposition to a cancer in a female mammal by detecting a nucleic acid molecule encoding BORIS. If Group XI is elected, these claims will be examined only to the extent that they relate to a nucleic acid.

Group XII, claim(s) 29 in part and 31, drawn to a method of diagnosing cancer or a predisposition to a cancer in a female mammal by detecting a polypeptide encoding BORIS. If Group XII is elected, these claims will be examined only to the extent that they relate to a polypeptide.

Group XIII, claim(s) 32, drawn to a method of prognosticating a cancer in a mammal.

Group XIV, claim(s) 33, drawn to a method of assessing the effectiveness of treatment of a cancer in a mammal.

Group XV, claim(s) 34 in part and 35, drawn to a method of treating a mammal prophylactically or therapeutically for cancer due to a nucleic acid molecule encoding BORIS. If Group XV is elected, these claims will be examined only to the extent that they relate to a nucleic acid.

Group XVI, claim(s) 34 in part and 36, drawn to a method of treating a mammal prophylactically or therapeutically for cancer due to a polypeptide molecule encoding BORIS. If Group XVI is elected, these claims will be examined only to the extent that they relate to a polypeptide.

Group XVII, claim(s) 38, drawn to a composition comprising a small molecule inhibitor of BORIS.

Group XVIII, claim(s) 39, drawn to a composition comprising an antibody inhibitor of BORIS.

Group XIX, claim(s) 40, drawn to a composition comprising an antisense molecule inhibitor of BORIS.

Group XX, claim(s) 41, drawn to a composition comprising a ribozyme inhibitor of BORIS.

2. Claim 37 link(s) inventions XVII-XX. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 37. Upon

the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. Inventions of Groups I-VII and XVII-XX represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The polynucleic acid of Group I, the complementary nucleic acid of Group II, the non-human nucleic acid of Group III, the non-human complementary nucleic acid of Group IV, the human polypeptide of Group V, the non-human polypeptide of Group VI, the antibody of Groups VII and XVIII, the small molecule of Group XVII, the antisense

molecule of Group XIX and the ribozyme of Group XX are all structurally and chemically different from each other. The polynucleotides are made by nucleic acid synthesis, while the polypeptides are made by translation of mRNA, the antibodies are raised by immunization and the ribozyme is made by transcription of DNA. Furthermore, the polynucleotide can be used for hybridization screening, the polypeptide can be used for methods of treatment, the antibody can be used to immunopurify the polypeptide and the small molecule can be used for different methods of treatment to up-regulate and down-regulate the polypeptide in a clinical setting, for example. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I-VII and XVII-XX are patentably distinct.

The methods of Inventions I and VIII-XVI differ in the method objectives, method steps and parameters and in the reagents used. Invention I recites diagnosing cancer by detecting BORIS nucleic acid in a male mammal; Invention VIII recites diagnosing cancer by detecting BORIS protein in a male mammal; Invention IX recites predicting a predisposition to cancer in an offspring of a male mammal by detecting BORIS nucleic acid; Invention X recites predicting a predisposition to cancer in an offspring of a male mammal by detecting BORIS protein; Invention XI recites diagnosing cancer in a female mammal by detecting BORIS nucleic acid; Invention XII recites diagnosing cancer in a female mammal by detecting BORIS protein; Invention XIII recites prognosticating a cancer in a mammal; Invention XIV recites assessing the effectiveness of treatment of cancer; Invention XV recites a cancer treatment in a cancer due to a nucleic acid and

Invention XVI recites a cancer treatment in a cancer due to a protein. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions I and VIII-XVI are separate and distinct in having different method steps and different endpoints and are patentably distinct.

Inventions II and IV and IX and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acids of Groups II and IV can be used in either of the methods of X or XII.

Inventions V, VI, and VII and VIII, X, and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the proteins and antibody of Groups V, VI and VII can be used in any of the methods of VIII, X, or XII.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

December 15, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER